

K960873

Physiometrix, Inc.
510(k), Premarket Notification
HydroSpot System, Model 1500 & 1501

SUMMARY OF SAFETY AND EFFECTIVENESS

Date: March 1, 1996

Company: Physiometrix, Inc.
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Subject Device: Model 1210 , Medium e-Net (48 - 54 cm)

Predicate Device: K930080, HydroDot NeuroMonitoring System

Classification: Class II, CFR 21 Part 882.1320, Cutaneous Electrodes

Description: The Medium e-Net is designed to fit patients with a head size in the range of 48 - 54 cm in circumference. It is constructed using the same materials and manufacturing processes as the larger sized net 54 - 62 cm) which is described in K930080.

Intended Use: The e-Net serves two functions as a part of the Hydro Dot NeuroMonitoring System. First, it locates the EEG electrodes according the 10-20 International System. Secondly, it conducts the electrical signal sensed by the electrodes from the skin to the EEG equipment.

Design/Materials: The Medium e-Net is fabricated from the same materials as the larger version. Only the size of the components was reduced to achieve the proportional fit on the intended head sizes.